E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2022-0069; FRL-10792-01-OCSPP]

Trinexapac-ethyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of trinexapac-ethyl in or on multiple commodities discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2022-0069, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Daniel Rosenblatt, Acting Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202)

566-1030; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2022-0069 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests

are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2022-0069, by one of the following methods:

• *Federal eRulemaking Portal*: *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of January 3, 2023 (88 FR 38) (FRL-9410-08-OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E8966) by IR-4, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The January 3, 2023, document supersedes the document published on April 28, 2022 (87 FR 25178) (FRL-9410-12-OCSPP). The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of trinexapac-ethyl in or on the raw agricultural commodities clover, forage at 8 parts per million (ppm) and clover, hay at 15 ppm. As a result of feeding clover that has been treated with trinexapac-ethyl to

livestock, the following tolerances were proposed in livestock commodities: cattle, fat and cattle, meat at 0.03 ppm; cattle, meat byproducts at 0.1 ppm; egg at 0.01 ppm; goat, fat and goat, meat at 0.03 ppm; goat, meat byproducts at 0.1 ppm; hog, meat byproducts at 0.1 ppm; milk at 0.01 ppm; horse, meat at 0.03 ppm; poultry, fat and poultry, meat at 0.01 ppm; poultry, meat byproducts at 0.1 ppm; sheep, fat and sheep, meat at 0.03 ppm; and sheep, meat byproducts at 0.1 ppm. That document referenced a summary of the petition, which is available in the docket, *https://www.regulations.gov*. A comment was received in response to the April 28, 2022, notice of filing. EPA's response to the comment is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for trinexapac-ethyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with trinexapac-ethyl follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings for the same

pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings for trinexapac-ethyl in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to trinexapac-ethyl and established tolerances for residues of that chemical. EPA is incorporating previously published sections from these rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the Toxicological Profile of trinexapac-ethyl, see Unit III.A. of the trinexapac-ethyl tolerance rulemaking published in the *Federal Register* of May 20, 2015 (80 FR 28843) (FRL-9926-62).

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern for trinexapac-ethyl used for human health risk assessment, please reference Unit III.B. of the trinexapac-ethyl tolerance rulemaking published in the *Federal Register* of March 2, 2012 (77 FR 12740) (FRL-9337-9).

Exposure assessment. EPA's dietary exposure assessments have been updated to include the additional exposure from the proposed new regional use on clover as well for associated residues on animal commodities. The assessments were conducted with Dietary Exposure Evaluation Model software using the Food Commodity Intake Database (DEEM-FCID) Version 4.02, which uses the 2005-2010 food consumption data from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The unrefined acute and chronic dietary exposure assessments used tolerance-level residues, EPA's default processing factors, and assumed 100 percent crop treated (PCT) for the registered commodities.

Drinking water and non-occupational exposures. The drinking water numbers have not

changed as a result of the new use on clover. For a detailed summary of the drinking water analysis for trinexapac-ethyl used for the human health risk assessment, please reference Unit III.C.2. of the May 20, 2015, rulemaking.

Trinexapac-ethyl is currently registered for the following uses that could result in residential exposures: residential lawns, athletic fields, parks, and golf courses. For a detailed summary of the non-occupational analysis for trinexapac-ethyl used for the human health risk assessment, please reference Unit III.C.3. of the May 20, 2015, rulemaking.

Cumulative exposure. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to trinexapac-ethyl and any other substances. For the purposes of this action, therefore, EPA has not assumed that trinexapac-ethyl has a common mechanism of toxicity with other substances.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor from 10X to 1X. See Unit III.D. of the May 20, 2015, rulemaking for a discussion of the Agency's rationale for that determination.

Aggregate risks and determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term aggregate risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD; they

are 2.5% of the aPAD for females 13 to 49 years old, the only population group of concern. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 6.8% of the cPAD for children 1 to 2 years old, the group with the highest exposure.

Short-term aggregate (average dietary and residential turf exposures) MOEs for adults (235) and youth (4,500) are above EPA's level of concern of 100 and are not of concern. Trinexapac-ethyl is classified as "not likely to be carcinogenic to humans." Therefore, EPA does not expect trinexapac-ethyl to pose a cancer risk from aggregate exposure.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to trinexapac-ethyl residues. More detailed information on this action can be found in the document titled "Trinexapac-ethyl. Human Health Risk Assessment for the New Use on Clover (Seed Crop)." in docket ID EPA-HQ-OPP-2022-0069.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the May 20, 2015, rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

There are no established Codex MRLs on clover forage and hay. There are established Codex MRLs for trinexapac-ethyl in or on livestock commodities. The U.S. tolerances are harmonized with Codex MRLs for ruminant and hog meat byproduct at 0.1 ppm. However, the

ruminant and swine meat and fat tolerances increased to 0.03 ppm because there is the potential for secondary transfer of trinexapac-ethyl resides in ruminant meat from the new use on clover. Because the U.S. tolerances are higher based on the estimated livestock dietary burden, it is not possible to harmonize with the 0.01 ppm Codex MRL for ruminant and swine meat and fat commodities.

C. Response to Comments

One comment was received on the notice of filing, which opposed EPA establishing the requested tolerances and objected to the presence of pesticide residues on crops. Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerances are safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that the trinexapac-ethyl tolerances are safe. The commenter has provided no information indicating that a safety determination cannot be supported.

V. Conclusion

Therefore, tolerances are established for residues of trinexapac-ethyl in or on egg at 0.01 ppm; milk at 0.01 ppm; poultry, fat at 0.01 ppm; poultry, meat at 0.01 ppm; and poultry, meat byproducts at 0.1 ppm. The following established tolerances for residues of trinexapac-ethyl are revised to the specified levels: cattle, fat at 0.03 ppm; cattle, meat at 0.03 ppm; cattle, meat byproducts at 0.1 ppm; goat, fat at 0.03 ppm; goat, meat at 0.03 ppm; goat, meat byproducts at 0.1 ppm; hog, meat byproducts at 0.1 ppm; horse, meat at 0.03 ppm; sheep, fat at 0.03 ppm; sheep, meat at 0.03 ppm; and sheep, meat byproducts at 0.1 ppm. Additionally, tolerances with regional registrations are established for residues of trinexapac-ethyl in or on clover, forage at 8 ppm and clover, hay at 15 ppm.

As a housekeeping measure, EPA is removing the word “imported” from the commodity

entry for “Poppy, seed imported”, as unnecessary and redundant. Moreover, use of that adjective is not consistent with how EPA typically identifies tolerances for residues in or on imported commodities. The associated footnote 1 indicates that there are no U.S. registrations for use of trinexapac-ethyl on poppy seed; thus, the tolerance itself is intended to cover residues on imported commodities. Additionally, footnote 1 is being added to the table as identified in the March 15, 2018, final tolerance rule. The changes have no substantive effect and can be accomplished without further notice and comment.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and

responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 14, 2023.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Revise § 180.662 to read as follows:

§ 180.662 Trinexapac-ethyl; tolerances for residues.

(a) *General*. Tolerances are established for residues of the plant growth regulator, trinexapac-ethyl, including its metabolites and degradates, in or on the commodities in table 1 to this paragraph (a). Compliance with the tolerance levels specified in table 1 is to be determined by measuring only the free and conjugated forms of both trinexapac-ethyl, ethyl 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylate and trinexapac, 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylic acid, calculated as the stoichiometric equivalent of trinexapac-ethyl, in or on the commodity.

Table 1 to Paragraph (a)

Commodity	Parts per million
Barley, bran	2.5
Barley, grain	2.0
Barley, hay	0.8
Barley, straw	0.4
Cattle, fat	0.03
Cattle, meat	0.03
Cattle, meat byproducts	0.1
Egg	0.01
Goat, fat	0.03
Goat, meat	0.03
Goat, meat byproducts	0.1
Grass, forage	1.5
Grass, hay	4.0
Grass, seed screenings	40.0
Grass, straw	10.0
Hog, fat	0.02
Hog, meat	0.02
Hog, meat by-products	0.1

Horse, fat	0.02
Horse, meat	0.03
Horse, meat byproducts	0.04
Milk	0.01
Oat, forage	1.0
Oat, grain	4.0
Oat, hay	1.5
Oat, straw	0.9
Poppy, seed[1]	8
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, meat byproducts	0.1
Rice, bran	1.5
Rice, grain	0.4
Rice, straw	0.07
Rice, wild, grain	0.4
Rye, bran	6.0
Rye, grain	4.0
Rye, hay	1.5
Rye, straw	0.9
Sheep, fat	0.03
Sheep, meat	0.03
Sheep, meat byproducts	0.1
Sugarcane, cane	1.5
Sugarcane, molasses	5
Wheat, bran	6.0
Wheat, forage	1.0
Wheat, grain	4.0
Wheat, hay	1.5
Wheat, middlings	10.5
Wheat, straw	0.9

[1] There are no U.S. registrations for Poppy, seed as of March 15, 2018.

(b) [Reserved]

(c) *Tolerances with regional registrations*. Tolerances with regional registrations, as defined in §180.1, are established for residues of trinexapac-ethyl, including its metabolites and degradates, in or on the commodities in table 2 to this paragraph (c). Compliance with the tolerance levels specified in table 2 is to be determined by measuring only the free and conjugated forms of both trinexapac-ethyl, ethyl 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylate and trinexapac, 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylic acid, calculated as the stoichiometric equivalent of trinexapac-ethyl, in or on the commodity.

Table 2 to Paragraph (c)

Commodity	Parts per million
Clover, forage	8
Clover, hay	15

(d) [Reserved]

[FR Doc. 2023-06409 Filed: 3/28/2023 8:45 am; Publication Date: 3/29/2023]